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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,736

09/21/2006

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BED001

7789

27137 7590 03/21/2008  
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EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,736	<b>Applicant(s)</b> BEDARD ET AL.	
	<b>Examiner</b> Leigh McKane	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robitaille et al. (US 2002/0085950) in view of Hennebert et al. (US 4,764,351).

With respect to claims 1, 6, 7, and 8-10, claims 1 and 6 are written in Jepson claim format, which is an admission that the limitations recited in the preamble up to the phrase “the improvement comprising,” are considered to be known prior art. In any event, Robitaille et al. teaches essentially the claimed method wherein an article to be sterilized may be exposed to repeated cycles of a vacuum (0.5-2 mbar) followed by humidified ozone. See Figure 3; paragraphs [0013]-[0032]. The sterilization chamber is maintained at a temperature of 20-35 °C (paragraph [0053]). Robitaille et al. further discloses that “the high relative humidity level combined with temperature differentials between walls and/or the load may lead to water condensation.” See paragraph [0039]. Robitaille et al. is silent with respect to removing condensation during the sterilization cycle between successive exposures to the humidified ozone.

Hennebert et al. discloses a method of gaseous sterilization and teaches that “the damaging role of water condensation has also been demonstrated. Some manufacturers of apparatuses for low temperature sterilization have tried to avoid the problems due to water

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condensation by automatically purging condensates during the sterilization cycle.” See col.2, lines 1-6. As Hennebert et al. evidences that it was known in the art at the time of the invention to remove condensates using automatic purges during the sterilization cycle, it would have been obvious to do the same in the method of Robitaille et al. as an additional means to avoid the problems associated with water condensation. One would have had an expectation of success when making the combination of Robitaille et al. with Hennebert et al..

With respect to claims 2-4 and 11-13, Hennebert et al. does not teach how the condensate is purged. However, Robitaille et al. already discloses a method of removing humidity at the end of the sterilization cycle by flushing with repeated pulses of oxygen. See paragraph [061]. It would have been obvious to use this same means of removing condensates in the manner suggested by Hennebert et al..

As to claims 5 and 14, Robitaille et al. discloses temperature equalization at the beginning of the sterilization process but not between cycles. See paragraph [0030]. However, as Robitaille et al. also teaches that temperature differentials are a cause of water condensation (paragraph [0039]), it would yielded predictable results to also equalize the temperature between cycles as a further means of reducing water condensation.

### ***Response to Arguments***

3. Applicant's arguments filed 7 December 2007 have been fully considered but they are not persuasive.
4. Applicant argues on pages 3-4 of the Response that Robitaille et al. discloses that the problems associated with condensation are resolved by temperature equalization and fails to

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suggest any other solution to the problem of condensation. The Examiner recognized this deficiency in Robitaille et al. but respectfully submits that Robitaille et al. was not used as an anticipatory reference. In fact, Robitaille et al. was combined with Hennebert et al. which teaches that it was known in the art at the time of the invention to avoid the problems due to water condensation in low temperature sterilization procedures by automatically purging condensates *during* the sterilization cycle. See col.2, lines 3-6. Thus, one of ordinary skill in the art would have recognized from the teachings of Hennebert et al. that one could *also* resolve condensation problems by purging condensates during the sterilization process and moreover, that the results of doing so would have been both apparent and evident.

5. On page 5 of the Response, Applicant contends that with respect to an oxygen flush, Robitaille et al. uses the oxygen only as a filling gas, not in a flushing step. However, the Examiner directs Applicant's attention to paragraph [0066] wherein Robitaille et al. teaches that the oxygen gas is used in a ventilation phase wherein the ventilation phase is intended to dry the sterilized materials and remove ozone residues.

6. Applicant submits on pages 5-6 of the Response that the prior art references fail to recognize the problem of condensation after a first or subsequent cycle. Nevertheless, Hennebert et al. does propose another solution to the problem of condensation during low temperature cycles. Further, it has been held that the mere fact that the references fails to evince an appreciation of the problem identified and solved by the applicant is not, standing alone, conclusive evidence of the nonobviousness of the claimed subject matter. The references may suggest doing, what an applicant has done, even though workers in the art were ignorant of the

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existence of the problem. In re Gershon, 152 USPQ 602 (CCPA 1967). Clearly, in this case, Hennebert et al. has suggested doing what applicant has done.

7. On page 7 of the Response, Applicant alleges that Hennebert et al. is non-analogous art. However, both Hennebert et al. and Robitaille et al. address the problem of condensation in low-temperature sterilization.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/  
Primary Examiner, Art Unit 1797

elm  
16 March 2008